

JUN - 8 2000

K000842

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

CADD-Prizm® PCS II Model 6101 Ambulatory Infusion System

March 14, 2000

I. GENERAL INFORMATION

Applicant's Name and Address: SIMS Deltec, Inc.
1265 Grey Fox Road
St. Paul, MN 55112

Contact Person: Lisa Stone
Manager, Regulatory Affairs

Common/Usual Name: Ambulatory Infusion Pump

Proprietary Name: CADD-Prizm® PCS II Model 6101 Ambulatory
Infusion System

Equivalence Device Comparison: CADD-Prizm® PCS Model 6101 Ambulatory
Infusion System

II. DEVICE DESCRIPTION

The CADD-Prizm® PCS II Model 6101 ambulatory infusion pump is similar in design, function, and intended use to Deltec's CADD-Prizm® PCS Model 6101 ambulatory infusion pump. The pump provides measured drug delivery for intravenous, subcutaneous, epidural space or subarachnoid space delivery to patients in hospital or outpatient settings. The pump can be programmed to deliver medication at a constant rate and/or to allow delivery of a bolus dose at a specified time interval.

III. INTENDED USE OF DEVICE

The CADD-Prizm® PCS II pump is indicated for intravenous, subcutaneous, epidural space, or subarachnoid space infusion. The pump is intended for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both (such as patient-controlled analgesia).

IV. DEVICE COMPARISON

	CADD-Prizm[®] PCS II Model 6101 Pump	CADD-Prizm[®] PCS Model 6101 Pump
Manufacturer	SIMS Deltec, Inc	SIMS Deltec, Inc
510(k) Notification Number (Substantial Equivalent Date)	TBD	K943310 February 21, 1995

INDICATIONS		
Intravenous	Yes	Yes
Subcutaneous	Yes	Yes
Epidural	Yes	Yes
Subarachnoid	Yes	Yes
Intraperitoneal	Yes	Yes
Intra-arterial	Yes	Yes

SYSTEM FEATURES		
Internal clock	Yes	Yes
Remote dose cord	Yes	Yes
AC Adapter	Yes	Yes
Air Detector	Yes	Yes
Reservoir Enclosure	Yes	Yes
Pole Mount Bracket	Yes	Yes
Pump Pouches	Yes	Yes
Dual Lock/Latch Mechanism	Yes	Yes
Printing Capabilities	Yes	Yes
Remote Communications Capabilities	Yes	Yes

SYSTEM COMPONENTS		
Microcomputer controlled pump	Yes	Yes
Medication reservoir (volume)	Yes	Yes
Administration Set (Air eliminating filter, 1.2µ/0.2µ)	Yes	Yes
Air-in-line detector	Yes	Yes
Size of air bubble:	100 µL or greater	100 µL or greater
Channels	1	1

PROGRAMMING FUNCTIONS		
Continuous Infusion	Yes	Yes
Continuous Infusion with bolus (PCA)	Yes	Yes
Security	Yes	Yes
Demand Dose Lockout	Yes	Yes
Delivery Limit	Yes	No
Programmable Titration Limits	Yes	Yes
Titration feature available while running	Yes	No
Pain Scale feature	Yes	No
Programmable Maximum Rate	Yes	No
Programmable End-of-Infusion Warning	Yes	No
Epidural Mode	Yes	No

510(k) Summary of Safety and Effectiveness
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Manufacturer	SIMS Deltec, Inc	SIMS Deltec, Inc
510(k) Notification Number (Substantial Equivalent Date)	TBD	K943310 February 21, 1995

MECHANICAL SPECIFICATIONS		
Pumping mechanism	Linear Peristaltic	Linear Peristaltic
Size	1.5 in. by 3.5 in. by 5.3 in.	1.5 in. by 3.5 in. by 5.3 in.
Weight	17 oz.	17 oz.
Internal power source	9V alkaline or lithium battery	9V alkaline or lithium battery
System delivery accuracy (nominal)	± 6%	± 6%
Ambulatory	Yes	Yes

ALARMS		
Low Battery	Yes	Yes
Depleted Battery	Yes	Yes
No-battery alert	Yes	Yes
Pump in stop mode	Yes	Yes
High pressure	Yes	Yes
Power up fault	Yes	Yes
Low volume in medication reservoir	Yes	Yes
Cassette detachment	Yes	Yes
Upstream occlusion	Yes	Yes
Air-in-line	Yes	Yes
Key Stuck	Yes	Yes
End-of-Infusion	Yes	Yes
Programmable End-of-Infusion Alarm	Yes	No

INFUSION SPECIFICATIONS – CONTINUOUS INFUSION WITH BOLUS		
Minimum Continuous Delivery rate	0 ml/hr	0 ml/hr
Maximum Continuous Delivery rate	30 ml/hr	30 ml/hr
Maximum Patient Bolus	9.9 mL	9.9 mL
Maximum Clinician Bolus	20 mL	20 mL
Reservoir volume	1 to 9999 mL	1 to 9999 mL
Patient Controlled Access (Dosing)	Yes	Yes
Dose lockout time	Yes	Yes
Doses per Hour Limit	No	Yes
Delivery Limit	Yes	No
Clinician Bolus	Yes	Yes
Programmable Maximum Delivery Rate (Continuous Rate + Bolus)	Yes	No

V. SUMMARY OF STUDIES

A. Functional Testing

Test plans associated with software validation, verification of software controlled programming functions, and software related to proper pump operation were certified for the CADD-Prizm® PCS II Ambulatory Infusion System.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the use of the CADD-Prizm[®] PCS II Ambulatory Infusion System.

C. Conclusions Drawn from Studies

Based upon the information provided above, the CADD-Prizm[®] PCS II Ambulatory Infusion System is substantially equivalent to other commercially available ambulatory infusion systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2000

Ms. Lisa J. Stone
Manager, Regulatory Affairs
Sims Deltec, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K000842

Trade Name: CADD-Prizm® PCS II Model 6101 Ambulatory
Infusion System
Regulatory Class: II
Product Code: FRN
Dated: March 14, 2000
Received: March 15, 2000

Dear Ms. Stone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

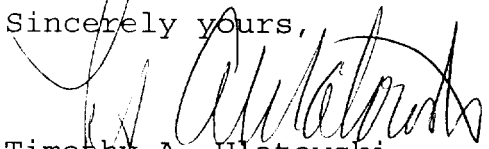
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Stone

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 000 842

Device Name: CADD-Prizm® PCS II Model 6101 Ambulatory Infusion Pump

Indications for Use:

" The CADD-Prizm® PCS II pump is indicated for intravenous, subcutaneous, epidural space, or subarachnoid space infusion. The pump is intended for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both (such as patient-controlled analgesia)."

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cuente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 000 842

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____